

PUBLIC HEALTH SERVICE
COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT

This Cooperative Research and Development Agreement, hereinafter referred to as "CRADA," consists of this Cover Page, an attached Agreement, and various Appendices referenced in the Agreement. This Cover Page serves to identify the Parties to this CRADA:

(1) the following Bureau(s), Institute(s), Center(s) or Division(s) of the National Institutes of Health ("NIH"), the Food and Drug Administration ("FDA"), and the Centers for Disease Control and Prevention ("CDC"):

, hereinafter singly or collectively referred to

as the Public Health Service ("PHS"); and

(2) _____, which has offices at

, hereinafter referred to as the "Collaborator."

COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT

Article 1. Introduction

This Cooperative Research and Development Agreement (CRADA) between PHS and Collaborator will be effective when signed by all Parties. The research and development activities which will be undertaken by each of the Parties in the course of this CRADA are detailed in the Research Plan (RP) which is attached as Appendix A. The funding and staffing commitments of the Parties are set forth in Appendix B. Any exceptions or modifications to the CRADA are set forth in Appendix C.

Article 2. Definitions

As used in this CRADA, the following terms shall have the indicated meanings:

- 2.1 "Affiliate" means any corporation or other business entity controlled by, controlling, or under common control with Collaborator. For this purpose, "control" means direct or indirect beneficial ownership of at least fifty (50) percent of the voting stock or at least fifty (50) percent interest in the income of such corporation or other business.
- 2.2 "Cooperative Research and Development Agreement" or "CRADA" means this Agreement, entered into by PHS pursuant to the Federal Technology Transfer Act of 1986, as amended, 15 U.S.C. 3710a et seq. and Executive Order 12591 of October 10, 1987.
- 2.3 "Government" means the Government of the United States as represented through the PHS agency that is a Party to this agreement.
- 2.4 "IP" means intellectual property.
- 2.5 "Invention" means any invention or discovery which is or may be patentable or otherwise protected under 35 U.S.C., or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321 et seq.).
- 2.6 "Principal Investigator(s)" or "PIs" means the person or persons designated respectively by each of the Parties to this CRADA who will be responsible for the scientific and technical conduct of the Research Plan.
- 2.7 "Proprietary/Confidential Information" means confidential scientific, business, or financial information provided that such information does not include:
 - 2.7.1 information that is publicly known or available from other sources who are not under a confidentiality obligation to the source of the information;
 - 2.7.2 information which has been made available by its owners to others without a confidentiality obligation;
 - 2.7.3 information which is already known by or available to the receiving Party without a

confidentiality obligation; or

- 2.7.4 information which relates to potential hazards or cautionary warnings associated with the production, handling or use of the subject matter of the Research Plan of this CRADA.
- 2.8 "*Research Materials*" means all tangible materials other than Subject Data first produced in the performance of this CRADA.
- 2.9 "*Research Plan*" or "*RP*" means the statement in Appendix A of the respective research and development commitments of the Parties to this CRADA.
- 2.10 "*Subject Data*" means all recorded information first produced in the performance of this CRADA by the Parties.
- 2.11 "*Subject Invention*" means any Invention of the Parties, conceived or first actually reduced to practice in the performance of the Research Plan of this CRADA.

Article 3. Cooperative Research

- 3.1 *Principal Investigators.* PHS research work under this CRADA will be performed by the PHS laboratory identified in the RP, and the PHS Principal Investigator (PI) designated in the RP will be responsible for the scientific and technical conduct of this project on behalf of PHS. Also designated in the RP is the Collaborator PI who will be responsible for the scientific and technical conduct of this project on behalf of the Collaborator.
- 3.2 *Research Plan Change.* The RP may be modified by mutual written consent of the Principal Investigators. Substantial changes in the scope of the RP will be treated as amendments under Article 13.6.

Article 4. Reports

- 4.1 *Interim Reports.* The Parties shall exchange formal written interim progress reports on a schedule agreed to by the PIs, but at least within twelve (12) months after this CRADA becomes effective and at least within every twelve (12) months thereafter. Such reports shall set forth the technical progress made, identifying such problems as may have been encountered and establishing goals and objectives requiring further effort, any modifications to the Research Plan pursuant to Article 3.2, and all CRADA-related patent applications filed.
- 4.2 *Final Reports.* The Parties shall exchange final reports of their results within four (4) months after completing the projects described in the RP or after the expiration or termination of this CRADA.

Article 5. Financial and Staffing Obligations

- 5.1 *PHS and Collaborator Contributions.* The contributions of the Parties, including payment schedules, if applicable, are set forth in Appendix B. PHS shall not be obligated to perform any of the research specified herein or to take any other action required by this CRADA if the funding is not provided as set forth in Appendix B. PHS shall return excess funds to the Collaborator when it sends its final fiscal

report pursuant to Article 5.2, except for staffing support pursuant to Article 10.3. Collaborator acknowledges that the U.S. Government will have the authority to retain and expend any excess funds for up to one (1) year subsequent to the expiration or termination of the CRADA to cover any costs incurred during the term of the CRADA in undertaking the work set forth in the RP.

- 5.2 *Accounting Records.* PHS shall maintain separate and distinct current accounts, records, and other evidence supporting all its obligations under this CRADA, and shall provide the Collaborator a final fiscal report pursuant to Article 4.2.
- 5.3 *Capital Equipment.* Equipment purchased by PHS with funds provided by the Collaborator shall be the property of PHS. All capital equipment provided under this CRADA by one party for the use of another Party remains the property of the providing Party unless other disposition is mutually agreed upon by in writing by the Parties. If title to this equipment remains with the providing Party, that Party is responsible for maintenance of the equipment and the costs of its transportation to and from the site where it will be used.

Article 6. Intellectual Property Rights and Patent Applications

- 6.1 *Reporting.* The Parties shall promptly report to each other in writing each Subject Invention resulting from the research conducted under this CRADA that is reported to them by their respective employees. Each Party shall report all Subject Inventions to the other Party in sufficient detail to determine inventorship. Such reports shall be treated as Proprietary/Confidential Information in accordance with Article 8.4.
- 6.2 *Collaborator Employee Inventions.* If the Collaborator does not elect to retain its IP rights, the Collaborator shall offer to assign these IP rights to the Subject Invention to PHS pursuant to Article 6.5. If PHS declines such assignment, the Collaborator may release its IP rights as it may determine.
- 6.3 *PHS Employee Inventions.* PHS on behalf of the U.S. Government may elect to retain IP rights to each Subject Invention made solely by PHS employees. If PHS does not elect to retain IP rights, PHS shall offer to assign these IP rights to such Subject Invention to the Collaborator pursuant to Article 6.5. If the Collaborator declines such assignment, PHS may release IP rights in such Subject Invention to its employee inventors pursuant to Article 6.6.
- 6.4 *Joint Inventions.* Each Subject Invention made jointly by PHS and Collaborator employees shall be jointly owned by PHS and the Collaborator. The Collaborator may elect to file the joint patent or other IP application(s) thereon and shall notify PHS promptly upon making this election. If the Collaborator decides to file such applications, it shall do so in a timely manner and at its own expense. If the Collaborator does not elect to file such application(s), PHS on behalf of the U.S. Government shall have the right to file the joint application(s) in a timely manner and at its own expense. If either Party decides not to retain its IP rights to a jointly owned Subject Invention, it shall offer to assign such rights to the other Party pursuant to Article 6.5. If the other Party declines such assignment, the offering Party may release its IP rights as provided in Articles 6.2, 6.3, and 6.6.
- 6.5 *Filing of Patent Applications.* With respect to Subject Inventions made by the Collaborator as described in Article 6.2, or by PHS as described in Article 6.3, a Party exercising its right to elect to retain IP rights to a Subject Invention agrees to file patent or other IP applications in a timely manner and at its own expense and after consultation with the other Party. The Party shall notify the other Party of its decision regarding filing in countries other than the United States in a timely manner. The Party may elect not

to file a patent or other IP application thereon in any particular country or countries provided it so advises the other Party ninety (90) days prior to the expiration of any applicable filing deadline, priority period or statutory bar date, and hereby agrees to assign its IP right, title and interest in such country or countries to the Subject Invention to the other Party and to cooperate in the preparation and filing of a patent or other IP applications. In any countries in which title to patent or other IP rights is transferred to the Collaborator, the Collaborator agrees that PHS inventors will share in any royalty distribution that the Collaborator pays to its own inventors.

- 6.6 *Release to Inventors.* In the event neither of the Parties to this CRADA elects to file a patent or other IP application on a Subject Invention, either or both (if a joint invention) may retain or release their IP rights in accordance with their respective policies and procedures. However, the Government shall retain a nonexclusive, non-transferrable, irrevocable, royalty-free license to practice any such Subject Invention or have it practiced throughout the world.
- 6.7 *Patent Expenses.* The expenses attendant to the filing of patent or other IP applications generally shall be paid by the Party filing such application. If an exclusive license to any Subject Invention is granted to the Collaborator, the Collaborator shall be responsible for all past and future out-of-pocket expenses in connection with the preparation, filing, prosecution and maintenance of any applications claiming such exclusively-licensed inventions and any patents or other IP grants that may issue on such applications. The Collaborator may waive its exclusive license rights on any application, patent or other IP grant at any time, and incur no subsequent compensation obligation for that application, patent or IP grant.
- 6.8 *Prosecution of Intellectual Property Applications.* Within one month of receipt or filing, each Party shall provide the other Party with copies of the applications and all documents received from or filed with the relevant patent or other IP office in connection with the prosecution of such applications. Each Party shall also provide the other Party with the power to inspect and make copies of all documents retained in the patent or other IP application files by the applicable patent or other IP office. Where licensing is contemplated by Collaborator, the Parties agree to consult with each other with respect to the prosecution of applications for PHS Subject Inventions described in Article 6.3 and joint Subject Inventions described in Article 6.4. If the Collaborator elects to file and prosecute IP applications on joint Subject Inventions pursuant to Article 6.4, PHS will be granted an associate power of attorney (or its equivalent) on such IP applications.

Article 7. Licensing

- 7.1 *Option for Commercialization License.* With respect to Government IP rights to any Subject Invention not made solely by the Collaborator's employees for which a patent or other IP application is filed, PHS hereby grants to the Collaborator an option to elect an exclusive or nonexclusive commercialization license, which is substantially in the form of the appropriate model PHS license agreement. This option does not apply to Subject Inventions conceived prior to the effective date of this CRADA that are reduced to practice under this CRADA, if prior to that reduction to practice, PHS has filed a patent application on the invention and has licensed it or offered to license it to a third party. The terms of the license will fairly reflect the nature of the invention, the relative contributions of the Parties to the invention and the CRADA, the risks incurred by the Collaborator and the costs of subsequent research and development needed to bring the invention to the marketplace. The field of use of the license will be commensurate with the scope of the RP.
- 7.2 *Exercise of License Option.* The option of Article 7.1 must be exercised by written notice mailed within

three (3) months after either (i) Collaborator receives written notice from PHS that the patent or other IP application has been filed; or (ii) the date Collaborator files such IP application; whichever comes first. Exercise of this option by the Collaborator initiates a negotiation period that expires nine (9) months after the exercise of the option. If the last proposal by the Collaborator has not been responded to in writing by PHS within this nine (9) month period, the negotiation period shall be extended to expire one (1) month after PHS so responds, during which month the Collaborator may accept in writing the final license proposal of PHS. In the absence of such acceptance, PHS will be free to license such IP rights to others. In the event that the Collaborator elects the option for an exclusive license, but no such license is executed during the negotiation period, PHS agrees not to make an offer for an exclusive license on more favorable terms to a third party for a period of six (6) months without first offering Collaborator those more favorable terms.

- 7.3 *License for PHS Employee Inventions and Joint Inventions.* Pursuant to 15 U.S.C. 3710a(b)(1)(A), for inventions made by PHS employees or jointly with a Collaborator under this CRADA, pursuant to Articles 6.3 and 6.4, the Collaborator grants to PHS a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government. In the exercise of such license, the Government shall not publicly disclose trade secrets or commercial or financial information that is privileged or confidential within the meaning of 5 U.S.C. 552(b)(4) or which would be considered as such if it had been obtained from a non-Federal party.
- 7.4 *License in Collaborator Inventions.* Pursuant to 15 U.S.C. 3710a(b)(2), for inventions made solely by Collaborator employees under this CRADA, pursuant to Article 6.2, the Collaborator grants to PHS a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government for research or other Government purposes.
- 7.5 *Third Party License.* Pursuant to 15 U.S.C. 3710a(1)(B), if PHS grants an exclusive license to a Subject Invention made wholly by PHS employees or jointly with a Collaborator under this CRADA, pursuant to Articles 6.3 and 6.4, the Government shall retain the right to require the Collaborator to grant to a responsible applicant a nonexclusive, partially exclusive, or exclusive sublicense to use the invention in Collaborator's licensed field of use on terms that are reasonable under the circumstances; or if the Collaborator fails to grant such a license, to grant the license itself. The exercise of such rights by the Government shall only be in exceptional circumstances and only if the Government determines (i) the action is necessary to meet health or safety needs that are not reasonably satisfied by Collaborator, (ii) the action is necessary to meet requirements for public use specified by Federal regulations, and such requirements are not reasonably satisfied by the Collaborator; or (iii) the Collaborator has failed to comply with an agreement containing provisions described in 15 U.S.C. 3710a(c)(4)(B). The determination made by the Government under this Article is subject to administrative appeal and judicial review under 35 U.S.C. 203(2).
- 7.6 *Joint Inventions Not Exclusively Licensed.* In the event that the Collaborator does not acquire an exclusive commercialization license to IP rights in all fields in joint Subject Inventions described in Article 6.4, then each Party shall have the right to use the joint Subject Invention and to license its use to others in all fields not exclusively licensed to Collaborator. The Parties may agree to a joint licensing approach for such IP rights.

Article 8. Proprietary Rights and Publication

- 8.1 *Right of Access.* PHS and the Collaborator agree to exchange all Subject Data produced in the course of research under this CRADA, whether developed solely by PHS or jointly with the Collaborator. Research Materials will be shared equally by the Parties to the CRADA unless other disposition is agreed to by the Parties. All Parties to this CRADA will be free to utilize Subject Data and Research Materials for their own purposes, consistent with their obligations under this CRADA.
- 8.2 *Ownership of Subject Data and Research Materials.* Subject to the sharing requirements of Paragraph 8.1 and the regulatory filing requirements of Paragraph 8.3, the producing Party will retain ownership of and title to all Subject Inventions, all Subject Data and all Research Materials produced solely by their investigators. Jointly developed Subject Inventions, Subject Data and Research Materials will be jointly owned.
- 8.3 *Dissemination of Subject Data and Research Materials.* To the extent allowed under law, the Collaborator and PHS agree to use reasonable efforts to keep Subject Data and Research Materials confidential until published or until corresponding patent applications are filed. Any information that would identify human subjects of research or patients will always be maintained confidentially. Collaborator shall have the exclusive right to use any and all CRADA Subject Data in and for any regulatory filing by or on behalf of Collaborator, except that PHS shall have the exclusive right to use Subject Data for that purpose, and authorize others to do so, if the CRADA is terminated or if Collaborator abandons its commercialization efforts.
- 8.4 *Proprietary/Confidential Information.* Each Party agrees to limit its disclosure of Proprietary/Confidential Information to the amount necessary to carry out the Research Plan of this CRADA, and shall place a confidentiality notice on all such information. Confidential oral communications shall be reduced to writing within 30 days by the disclosing Party. Each Party receiving Proprietary/Confidential Information agrees that any information so designated shall be used by it only for the purposes described in the attached Research Plan. Any Party may object to the designation of information as Proprietary/Confidential Information by another Party. Subject Data and Research Materials developed solely by the Collaborator may be designated as Proprietary/Confidential Information when they are wholly separable from the Subject Data and Research Materials developed jointly with PHS investigators, and advance designation of such data and material categories is set forth in the RP. The exchange of other confidential information, e.g., patient-identifying data, should be similarly limited and treated. Jointly developed Subject Data and Research Material derived from the Research Plan may be disclosed by Collaborator to a third party under a confidentiality agreement for the purpose of possible sublicensing pursuant to the Licensing Agreement and subject to Article 8.7.
- 8.5 *Protection of Proprietary/Confidential Information.* Proprietary/Confidential Information shall not be disclosed, copied, reproduced or otherwise made available to any other person or entity without the consent of the owning Party except as required under court order or the Freedom of Information Act (5 U.S.C. 552). Each Party agrees to use its best efforts to maintain the confidentiality of Proprietary/Confidential Information. Each Party agrees that the other Party is not liable for the disclosure of Proprietary/Confidential Information which, after notice to and consultation with the concerned Party, the other Party in possession of the Proprietary/Confidential Information determines may not be lawfully withheld, provided the concerned Party has been given an opportunity to obtain a court order to enjoin disclosure.
- 8.6 *Duration of Confidentiality Obligation.* The obligation to maintain the confidentiality of Proprietary/Confidential Information shall expire at the earlier of the date when the information is no longer Proprietary Information as defined in Article 2.5 or three (3) years after the expiration or termination date of this CRADA. The Collaborator may request an extension to this term when

necessary to protect Proprietary/Confidential Information relating to products not yet commercialized.

- 8.7 *Publication.* The Parties are encouraged to make publicly available the results of their research. Before either Party submits a paper or abstract for publication or otherwise intends to publicly disclose information about a Subject Invention, Subject Data or Research Materials, the other Party shall be provided thirty (30) days to review the proposed publication or disclosure to assure that Proprietary/Confidential Information is protected. The publication or other disclosure shall be delayed for up to thirty (30) additional days upon written request by any Party as necessary to preserve U.S. or foreign patent or other IP rights.

Article 9. Representations and Warranties

- 9.1 *Representations and Warranties of PHS.* PHS hereby represents and warrants to the Collaborator that the official signing this CRADA has authority to do so.

- 9.2 *Representations and Warranties of the Collaborator.*

(a) The Collaborator hereby represents and warrants to PHS that the Collaborator has the requisite power and authority to enter into this CRADA and to perform according to its terms, and that the Collaborator's official signing this CRADA has authority to do so. The Collaborator further represents that it is financially able to satisfy any funding commitments made in Appendix B.

(b) The Collaborator certifies that the statements herein are true, complete, and accurate to the best of its knowledge. The Collaborator is aware that any false, fictitious, or fraudulent statements or claims may subject it to criminal, civil, or administrative penalties.

Article 10. Termination

- 10.1 *Termination By Mutual Consent.* PHS and the Collaborator may terminate this CRADA, or portions thereof, at any time by mutual written consent. In such event the Parties shall specify the disposition of all property, inventions, patent or other IP applications and other results of work accomplished or in progress, arising from or performed under this CRADA, all in accordance with the rights granted to the Parties under the terms of this Agreement.
- 10.2 *Unilateral Termination.* Either PHS or the Collaborator may unilaterally terminate this entire CRADA at any time by giving written notice at least thirty (30) days prior to the desired termination date, and any rights accrued in property, patents or other IP rights shall be disposed of as provided in paragraph 10.1.
- 10.3 *Staffing.* If this CRADA is mutually or unilaterally terminated prior to its expiration, funds will nevertheless remain available to PHS for continuing any staffing commitment made by the Collaborator pursuant to Article 5.1 above and Appendix B, if applicable, for a period of six (6) months after such termination. If there are insufficient funds to cover this expense, the Collaborator agrees to pay the difference.
- 10.4 *New Commitments.* No Party shall make new commitments related to this CRADA after a mutual termination or notice of a unilateral termination and shall, to the extent feasible, cancel all outstanding commitments and contracts by the termination date.

- 10.5 *Termination Costs.* Concurrently with the exchange of final reports pursuant to Articles 4.2 and 5.2, PHS shall submit to the Collaborator for payment a statement of all costs incurred prior to the date of termination and for all reasonable termination costs including the cost of returning Collaborator property or removal of abandoned property, for which Collaborator shall be responsible.

Article 11. Disputes

- 11.1 *Settlement.* Any dispute arising under this CRADA which is not disposed of by agreement of the Principal Investigators shall be submitted jointly to the signatories of this CRADA. If the signatories are unable to jointly resolve the dispute within thirty (30) days after notification thereof, the Assistant Secretary for Health (or his/her designee or successor) shall propose a resolution. Nothing in this Article shall prevent any Party from pursuing any additional administrative remedies that may be available and, after exhaustion of such administrative remedies, pursuing all available judicial remedies.
- 11.2 *Continuation of Work.* Pending the resolution of any dispute or claim pursuant to this Article, the Parties agree that performance of all obligations shall be pursued diligently in accordance with the direction of the PHS signatory.

Article 12. Liability

- 12.1 *Property.* The U.S. Government shall not be responsible for damages to any Collaborator property provided to PHS, where Collaborator retains title to the property, or any property acquired by Collaborator for its own use pursuant to this CRADA.
- 12.2 *NO WARRANTIES.* EXCEPT AS SPECIFICALLY STATED IN ARTICLE 9, THE PARTIES MAKE NO EXPRESS OR IMPLIED WARRANTY AS TO ANY MATTER WHATSOEVER, INCLUDING THE CONDITIONS OF THE RESEARCH OR ANY INVENTION OR PRODUCT, WHETHER TANGIBLE OR INTANGIBLE, MADE, OR DEVELOPED UNDER THIS CRADA, OR THE OWNERSHIP, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OF THE RESEARCH OR ANY INVENTION OR PRODUCT.
- 12.3 *Indemnification.* The Collaborator agrees to hold the U.S. Government harmless and to indemnify the Government for all liabilities, demands, damages, expenses and losses arising out of the use by the Collaborator for any purpose of the Subject Data, Research Materials and/or Subject Inventions produced in whole or part by PHS employees under this CRADA, unless due to the negligence or willful misconduct of PHS, its employees, or agents. The Collaborator shall be liable for any claims or damages it incurs in connection with this CRADA. PHS has no authority to indemnify the Collaborator.
- 12.4 *Force Majeure.* Neither Party shall be liable for any unforeseeable event beyond its reasonable control not caused by the fault or negligence of such Party, which causes such Party to be unable to perform its obligations under this CRADA, and which it has been unable to overcome by the exercise of due diligence. In the event of the occurrence of such a *force majeure* event, the Party unable to perform shall promptly notify the other Party. It shall further use its best efforts to resume performance as quickly as possible and shall suspend performance only for such period of time as is necessary as a result of the *force majeure* event.

Article 13. Miscellaneous

- 13.1 *Governing Law.* The construction, validity, performance and effect of this CRADA shall be governed by Federal law, as applied by the Federal Courts in the District of Columbia. Federal law and regulations will preempt any conflicting or inconsistent provisions in this CRADA.
- 13.2 *Entire Agreement.* This CRADA constitutes the entire agreement between the Parties concerning the subject matter of this CRADA and supersedes any prior understanding or written or oral agreement.
- 13.3 *Headings.* Titles and headings of the articles and subarticles of this CRADA are for convenient reference only, do not form a part of this CRADA, and shall in no way affect its interpretation.
- 13.4 *Waivers.* None of the provisions of this CRADA shall be considered waived by any Party unless such waiver is given in writing to the other Party. The failure of a Party to insist upon strict performance of any of the terms and conditions hereof, or failure or delay to exercise any rights provided herein or by law, shall not be deemed a waiver of any rights of any Party.
- 13.5 *Severability.* The illegality or invalidity of any provisions of this CRADA shall not impair, affect, or invalidate the other provisions of this CRADA.
- 13.6 *Amendments.* If either Party desires a modification to this CRADA, the Parties shall, upon reasonable notice of the proposed modification or extension by the Party desiring the change, confer in good faith to determine the desirability of such modification or extension. Such modification shall not be effective until a written amendment is signed by the signatories to this CRADA or by their representatives duly authorized to execute such amendment.
- 13.7 *Assignment.* Neither this CRADA nor any rights or obligations of any Party hereunder shall be assigned or otherwise transferred by either Party without the prior written consent of the other Party.
- 13.8 *Notices.* All notices pertaining to or required by this CRADA shall be in writing and shall be signed by an authorized representative and shall be delivered by hand or sent by certified mail, return receipt requested, with postage prepaid, to the addresses indicated on the signature page for each Party. Notices regarding the exercise of license options shall be made pursuant to Article 7.2. Any Party may change such address by notice given to the other Party in the manner set forth above.
- 13.9 *Independent Contractors.* The relationship of the Parties to this CRADA is that of independent contractors and not agents of each other or joint venturers or partners. Each Party shall maintain sole and exclusive control over its personnel and operations. Collaborator employees who will be working at PHS facilities may be asked to sign a Guest Researcher or Special Volunteer Agreement appropriately modified in view of the terms of this CRADA.
- 13.10 *Use of Name or Endorsements.* By entering into this CRADA, PHS does not directly or indirectly endorse any product or service provided, or to be provided, whether directly or indirectly related to either this CRADA or to any patent or other IP license or agreement which implements this CRADA by its successors, assignees, or licensees. The Collaborator shall not in any way state or imply that this CRADA is an endorsement of any such product or service by the U.S. Government or any of its organizational units or employees. Collaborator issued press releases that reference or rely upon the work of PHS under this CRADA shall be made available to PHS at least 7 days prior to publication for review and comment.
- 13.11 *Exceptions to this CRADA.* Any exceptions or modifications to this CRADA that are agreed to by the Parties prior to their execution of this CRADA are set forth in Appendix C.

- 13.12 *Reasonable Consent.* Whenever a Party's consent or permission is required under this CRADA, such consent or permission shall not be unreasonably withheld.

Article 14. Duration of Agreement

- 14.1 *Duration.* It is mutually recognized that the duration of this project cannot be rigidly defined in advance, and that the contemplated time periods for various phases of the RP are only good faith guidelines subject to adjustment by mutual agreement to fit circumstances as the RP proceeds. In no case will the term of this CRADA extend beyond the term indicated in the RP unless it is revised in accordance with Article 13.6.
- 14.2 *Survivability.* The provisions of Articles 4.2, 5-8, 10.3-10.5, 11.1, 12.2-12.4, 13.1, 13.10 and 14.2 shall survive the termination of this CRADA.

SIGNATURES

By executing this Agreement, each of the undersigned represents and confirms that he or she is fully authorized to bind the identified entity to its terms. Each of the undersigned expressly certifies or affirms that the contents of any statement made or reflected in this document are truthful and accurate.

AGREED TO AND ACCEPTED BY:

For the National Cancer Institute:

Alan Rabson, M.D.
Deputy Director, National Cancer Institute

Date

Address correspondence related to this Agreement to:

Sherry S. Ansher, Ph.D.
Coordinator, Research & Development Agreements
Regulatory Affairs Branch
Cancer Therapy Evaluation Program, DCTD
National Cancer Institute, NIH
6130 Executive Boulevard, Suite 718
Rockville, MD 20852
Telephone: 301-496-7912
Fax: 301-402-1584

For the Collaborator:

(Signature)

Date

(Printed Name and Title)

Address: